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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2013-0019]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0494]

Draft Interagency Risk Assessment - Listeria monocytogenes in Retail Delicatessens: Notice of Availability of Documents and Request for Comment

AGENCY: Food Safety and Inspection Service, United States

Department of Agriculture; Center for Food Safety and Applied Nutrition, Food and Drug Administration, HHS.

ACTION: Notice and request for comment.

SUMMARY: The United States Department of Agriculture (USDA)/ Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA)/ Center for Food Safety and Applied Nutrition (CFSAN) are announcing the availability of the draft "Interagency Risk Assessment - Listeria monocytogenes in Retail Delicatessens." This draft quantitative risk assessment (QRA) includes an Interpretive Summary and a Technical Report. The purpose of the draft QRA is to evaluate the conditions, such as

Listeria (L.) monocytogenes contamination of certain ready-to-eat (RTE) foods, for example cheese, deli meats, and deli salads; in the retail deli environment; in niches (a harborage site); or on incoming RTE foods, that contribute to cross-contamination and ultimately, to the risk of listeriosis. The draft QRA makes it possible to evaluate the effectiveness of some retail practices and intervention strategies in reducing the predicted risk of listeriosis from some RTE foods that are sliced, packaged, or prepared in retail delicatessens and consumed in the home.

DATES: Comments on the draft QRA should be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Comments to FSIS may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782,

Room 8-163A, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street SW, Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2013-0019. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW, Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

Comments to FDA: Interested persons may submit either electronic comments and scientific data and information to <http://www.regulations.gov> or written comments and scientific data and information to the Division of Dockets Management [(HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852]. It is only necessary to send one set of comments. Identify comments with the FDA docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management

between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

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FDA: Sherri Dennis, Acting Director, Division of Risk Assessment, Office of Analytics and Outreach, FDA/CFSAN, HFS-005, 5100 Paint Branch Parkway, College Park, Maryland 20740; Telephone: (240) 402-1914, E-mail: [Sherri.Dennis@fda.hhs.gov](mailto:Sherri.Dennis@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

## I. Background

Listeria monocytogenes (L. monocytogenes) is a widely occurring pathogen that persists in agricultural, food processing, and retail environments. Ingestion of L. monocytogenes can lead to the development of listeriosis, which could cause septicemia, meningitis, encephalitis, spontaneous abortion, and stillbirth. Epidemiological data show that listeriosis has one of the highest hospitalization rates (approximately 95 percent) and one of the highest case fatality

rates (approximately 16 percent) among foodborne diseases in the United States (Ref. 1).

To reduce listeriosis, it is important to identify: (1) which RTE foods pose the greatest risk to public health, and (2) which changes in practices are critical for reducing the prevalence and levels of L. monocytogenes in these RTE products. Risk assessment is a decision-support tool that has been used to successfully accomplish these goals by prioritizing RTE foods according to risk and linking food safety research to changes in practices that will improve public health outcomes.

A 2003 industry survey of L. monocytogenes in RTE foods purchased at retail grocery stores showed a seven-fold higher incidence and level of L. monocytogenes in deli meats sliced and served in retail delis compared to those sliced and packaged in manufacturing plants (Ref. 2). A subsequent survey by academia yielded similar findings (Ref. 3). An FSIS risk assessment, using these data, predicted an estimated 83 percent of all deli meat-related listeriosis cases are associated with deli meat sliced and packaged at retail delis (Ref. 4). A Cornell University comparative risk assessment had similar findings (Ref. 5).

Cross contamination in the deli environment is thought to contribute to L. monocytogenes contamination of RTE foods, but

little is known about the transfer of this pathogen from one surface to another in the retail setting. L. monocytogenes is present in the environment and can survive and grow in foods held at ambient and refrigeration temperatures. Therefore adequate preventive controls must take into account contamination as well as survival and proliferation of the organism. L. monocytogenes can contaminate foods via cross contamination from one product to another or through contamination from the environment, or both. FSIS and CFSAN (we) jointly developed a risk assessment to better understand L. monocytogenes transmission, survival, and growth in the retail environment and to evaluate how retail practices may impact public health. In 2009, the President's Food Safety Work Group identified this quantitative risk assessment (QRA) as a priority (Ref. 6).

## II. Draft Interagency Risk Assessment - L. monocytogenes in Retail Delicatessens

The draft "Interagency Risk Assessment - Listeria monocytogenes in Retail Delicatessens" (Ref. 7-8) provides federal risk managers and the retail industry with a science-based decision support tool to evaluate the effectiveness of retail practices and interventions to reduce or prevent listeriosis associated with the consumption of RTE foods

commonly prepared and sold in the delicatessen (deli) of a retail food store. It also examines how changes in current retail practices might further mitigate the predicted risk of listeriosis from these RTE foods. We conducted the draft QRA collaboratively, in consultation with the Centers for Disease Control and Prevention (CDC) and with input from industry, academic institutions, and consumer advocacy group stakeholders. It is available on FSIS's Web site at [http://www.fsis.usda.gov/PDF/Interagency\\_RA\\_Lm\\_Retail\\_Report\\_May\\_2013.pdf](http://www.fsis.usda.gov/PDF/Interagency_RA_Lm_Retail_Report_May_2013.pdf) and FDA's Web site at <http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm>.

The draft QRA model has undergone an independent external peer review consistent with the requirements for peer review in the Office of Management and Budget's "Final Information Quality Bulletin for Peer Review." Our response to the peer-review is available electronically on FSIS's Web site and FDA's Web site (Ref. 9).

The draft QRA answers the following three broad risk management questions:

1. What is the exposure to L. monocytogenes from consuming RTE foods prepared in retail delis?
2. What are the key processes that increase RTE foods contamination at retail delis?

3. How much is the relative risk per serving reduced according to specific risk management options?

The three risk management questions are very broad in nature, and we further refined them to a list of risk mitigations evaluated through scenario analyses within the QRA. We used specific risk management questions provided by federal partners and stakeholders to guide the simulation scenarios conducted with the QRA.

Specifically, the QRA model:

- considers L. monocytogenes entering the retail deli area from either contaminated incoming products or from environmental/niche contamination;
- considers a variety of RTE foods (e.g., different types of cheeses, deli meats, and deli salads) entering the retail deli;
- simulates the transmission of L. monocytogenes among multiple pathways (including product-to-slicers, gloves-to-display cases, and utensils-to-gloves);
- incorporates employee behaviors that contribute either to the spread or inactivation of L. monocytogenes (e.g., cleaning and sanitizing); and



- factors with the potential for affecting bacterial growth (e.g., temperature/time, product pH, water activity, presence of growth inhibitors).

The QRA also estimates the risk of listeriosis from the handling and consumption of these products in the home. The QRA models two subpopulations: (1) the subpopulation with increased susceptibility (including neonates, older adults, and the immunocompromised), and (2) the subpopulation with decreased susceptibility (the general healthy population).

We coordinated with CDC and several universities to gather data for the QRA. Stakeholders also developed partnerships to fill the data gaps identified in a request for scientific data and information for the project (Ref. 10). In 2009, we held a public meeting to present the background and data needs for this QRA (Ref. 11) (transcripts are available in the FSIS docket room and on the FSIS Web site at [http://www.fsis.usda.gov/PDF/Listeria-Transcript\\_062309.pdf](http://www.fsis.usda.gov/PDF/Listeria-Transcript_062309.pdf)). As announced by FSIS in the Federal Register (78 FR 23901; April 23, 2013), we will hold a second public meeting on May 22, 2013 to present the supporting data, modeling approach, and findings of the QRA. (More information about this meeting will be available on FSIS's website at <http://www.fsis.usda.gov/news/meetings & events/>).

### III. Request for Comments

We invite comments on the QRA that can help improve:

- the overall risk assessment approach used;
- the assumptions made;
- the modeling techniques;
- the data used; and
- the clarity and the transparency of the documentation in this draft QRA.

We will review and evaluate all public comments on this draft QRA and make modifications to the assessment based on comments, as appropriate.

### IV. References

The following references are on display in the FSIS Docket Room at the address above between 8:00 a.m. and 4:30 p.m., Monday through Friday, and in the FDA Division of Dockets Management at the address above between 9 a.m. and 4 p.m., Monday through Friday. (We have verified the following Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M.A., Roy, S.L., Jones, J.L., and Griffin, P.M.,

- Foodborne illness acquired in the United States—major pathogens. Emerging Infectious Diseases, 2011. 17(1): p. 7-12.
2. Gombas, D.E., Chen, Y., Clavero, R.S., and Scott, V.N., Survey of Listeria monocytogenes in ready-to-eat foods. Journal of Food Protection, 2003. 66(4): p. 559-69.
  3. Draughon, A.F. A collaborative analysis/risk assessment of Listeria monocytogenes in ready-to-eat processed meat and poultry collected in four FoodNet states in International Association for Food Protection 93rd Annual Meeting. 2006. Calgary, Alberta, Canada. Data shown in Endrikat et al. (2010) (Ref. 4).
  4. Endrikat, S., Gallagher, D., Pouillot, R., Hicks Quesenberry, H., Labarre, D., Schroeder, C.M., and Kause, J., A Comparative Risk Assessment for Listeria monocytogenes in Prepackaged versus Retail-Sliced Deli Meat. Journal of Food Protection, 2010. 73(4): p. 612-9.
  5. Pradhan, A.K., Ivanek, R., Grohn, Y.T., Bukowski, R., Geornaras, I., Sofos, J.N., and Wiedmann, M., Quantitative Risk Assessment of Listeriosis-Associated Deaths Due to Listeria monocytogenes Contamination of Deli Meats Originating from Manufacture and Retail. Journal of Food Protection, 2010. 73(4): p. 620-30.

6. Federal Food Safety Working Group, The Federal Food Safety Working Group Progress Report, 2011. p. 31. Available from: [http://www.whitehouse.gov/sites/default/files/fswg\\_report\\_final.pdf](http://www.whitehouse.gov/sites/default/files/fswg_report_final.pdf).
7. U.S. Department of Agriculture, Food Safety and Inspection Service and Department of Health and Human Service, Food and Drug Administration/ Center for Food Safety and Applied Nutrition. Draft Interagency Risk Assessment - Listeria monocytogenes in Retail Delicatessens: Interpretative Summary. May 2013.  
[http://www.fsis.usda.gov/PDF/Interagency\\_RA\\_Lm\\_Retail\\_Summary\\_May2013.pdf](http://www.fsis.usda.gov/PDF/Interagency_RA_Lm_Retail_Summary_May2013.pdf) and  
<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm>
8. U.S. Department of Agriculture, Food Safety and Inspection Service and Department of Health and Human Service, Food and Drug Administration/ Center for Food Safety and Applied Nutrition. Draft Interagency Risk Assessment - Listeria monocytogenes in Retail Delicatessens: Report. May 2013.  
[http://www.fsis.usda.gov/PDF/Interagency\\_RA\\_Lm\\_Retail\\_Report\\_May2013.pdf](http://www.fsis.usda.gov/PDF/Interagency_RA_Lm_Retail_Report_May2013.pdf) and  
<http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/default.htm>.

9. U.S. Department of Agriculture, Food Safety and Inspection Service and Department of Health and Human Service, Food and Drug Administration/ Center for Food Safety and Applied Nutrition. Draft Interagency Risk Assessment - Listeria monocytogenes in Retail Delicatessens: Response to Peer Review Comments. May 2013.

[http://www.fsis.usda.gov/PDF/Interagency\\_RA\\_Lm\\_Retail\\_Peer\\_Review\\_May2013.pdf](http://www.fsis.usda.gov/PDF/Interagency_RA_Lm_Retail_Peer_Review_May2013.pdf) and

<http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/>.

10. Federal Register Notice. Risk Assessment of the Public Health Impact from Foodborne Listeria monocytogenes in Some Ready-to-Eat Foods Sliced, Prepared, and/or Packaged in Retail Facilities; Request for Comments and for Scientific Data and Information. (74 FR 3617; January 21, 2009), Docket No. FDA-2008-N-0658,

<http://www.fda.gov/OHRMS/DOCKETS/98fr/E9-938.pdf>.

11. Interagency Retail Listeria monocytogenes Risk Assessment: Notice of a Public Meeting. (74 FR 27276; June 9, 2009).

Docket No. FSIS-2009-0012, <http://www.gpo.gov/fdsys/pkg/FR-2009-06-09/html/E9-13378.htm>.

#### Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at

[http://www.fsis.usda.gov/regulations\\_&\\_policies/Federal\\_Register\\_Notices/index.asp](http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp).

FSIS will also make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at

[http://www.fsis.usda.gov/News\\_&\\_Events/Email\\_Subscription/](http://www.fsis.usda.gov/News_&_Events/Email_Subscription/).

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Done at Washington, DC on:  
April 24, 2013.

Alfred V. Almanza,  
Administrator.

Leslie Kux,  
Assistant Commissioner for Policy, FDA.

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